



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,828	01/24/2002	Xianqiang Li	26757-707	4192

21971 7590 10/20/2003

WILSON SONSINI GOODRICH & ROSATI  
650 PAGE MILL ROAD  
PALO ALTO, CA 943041050

EXAMINER
----------

BYRD, DEVON R

ART UNIT	PAPER NUMBER
----------	--------------

1639

DATE MAILED: 10/20/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/057,828	Applicant(s) LI ET AL.	
	Examiner Devon R Byrd	Art Unit 1639	<i>FILE COPY</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 January 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-80 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

ART UNIT: 1639

DETAILED ACTION

*STATUS OF THE CLAIMS*

CLAIMS 1-80 ARE PENDING IN THE PRESENT APPLICATION AND ARE SUBJECT TO RESTRICTION AND ELECTION OF SPECIES REQUIREMENTS.

*ELECTION/RESTRICTIONS*

RESTRICTION TO ONE OF THE FOLLOWING INVENTIONS IS REQUIRED UNDER 35 U.S.C.

121:

- I. CLAIMS 1-22, DRAWN TO A LIBRARY OF NUCLEIC ACID CONSTRUCTS, CLASSIFIED IN CLASS 536, SUBCLASS 23.1 AND OTHER CLASSES DEPENDING UPON THE LENGTH AND CONTENT OF THE NUCLEIC ACIDS.
- II. CLAIMS 23-35, DRAWN TO A LIBRARY OF EXPRESSION VECTORS, CLASSIFIED IN CLASS 536, SUBCLASS 34.1 AND OTHER CLASSES DEPENDING UPON THE LENGTH AND CONTENT OF THE NUCLEIC ACIDS.
- III. CLAIMS 36-48, DRAWN TO A LIBRARY OF CELLS, CLASSIFIED IN CLASS 435, SUBCLASS 489; CLASS 435, SUBCLASS 260.2 AND OTHER CLASSES DEPENDING UPON THE LENGTH AND CONTENT OF THE NUCLEIC ACIDS.
- IV. CLAIMS 49-57 AND 78, DRAWN TO A KIT COMPRISING A LIBRARY OF NUCLEIC ACID CONSTRUCTS, CLASSIFIED IN CLASS 536, SUBCLASS 23.1, CLASS 536, SUBCLASS 24.3, AND OTHER CLASSES DEPENDING UPON THE LENGTH AND CONTENT OF THE NUCLEIC ACIDS.
- V. CLAIMS 58-67 AND 79, DRAWN TO A LIBRARY OF EXPRESSION VECTORS, CLASSIFIED IN CLASS 536, SUBCLASS 34.1, CLASS 536, SUBCLASS 24.3, AND OTHER CLASSES DEPENDING UPON THE LENGTH AND CONTENT OF THE NUCLEIC ACIDS.

ART UNIT: 1639

VI. CLAIMS 68-77 AND 80, DRAWN TO A LIBRARY OF CELLS, CLASSIFIED IN CLASS 435, SUBCLASS 489, CLASS 536, SUBCLASS 24.3, AND OTHER CLASSES DEPENDING UPON THE LENGTH AND CONTENT OF THE NUCLEIC ACIDS.

THE ABOVE INVENTIONS ARE DISTINCT, EACH FROM THE OTHER BECAUSE OF THE FOLLOWING REASONS: THE ABOVE INVENTIVE GROUPS ARE DIRECTED TO DIFFERENT PRODUCTS, RESTRICTION IS DEEMED PROPER BECAUSE THESE PRODUCTS CONSTITUTE PATENTABLY DISTINCT INVENTIONS FOR THE FOLLOWING REASONS: GROUPS I-VI ARE DIRECTED TO PRODUCTS THAT ARE DISTINCT BOTH PHYSICALLY AND FUNCTIONALLY, ARE NOT REQUIRED FOR ONE ANOTHER, HAVE DIFFERENT CLASSIFICATION, AND ARE THEREFORE PATENTABLY DISTINCT.

THE CIS ELEMENT LIBRARIES OF GROUPS I-VI COMPRISE MOLECULES THAT DIFFER IN LENGTH AND NUCLEIC ACID CONTENT AND THUS CONSTITUTE PATENTABLY DISTINCT COMPOUNDS WHICH MAY POSSESS DIFFERENT PHYSICOCHEMICAL PROPERTIES AND/OR METHODS OF MANUFACTURE.

ADDITIONALLY, NUCLEIC ACIDS COMPRISING VARIABLE SEQUENCES DO NOT CONSTITUTE COMPOUNDS THAT CONTAIN A COMMON CORE STRUCTURE ESSENTIAL TO A COMMON UTILITY.

BECAUSE THESE INVENTIONS ARE DISTINCT FOR THE REASONS GIVEN ABOVE, AND

- A. HAVE ACQUIRED A SEPARATE STATUS IN THE ART AS SHOWN BY THEIR DIFFERENT CLASSIFICATION; AND
- B. HAVE DIVERGENT SUBJECT MATTER; AND
- C. HAVE DIFFERENT AND SEPARATELY BURDENSOME MANUAL AND/OR COMPUTER STRUCTURE, NAME, AND BIBLIOGRAPHICAL SEARCHES; AND

ART UNIT: 1639

SINCE THE LACK OF A COMMON CORE RENDERS THE SEARCH UNDULY BURDENSOME (FOR EXAMPLE, SEARCHING A CLAIM THAT READS ON AN INFINITE NUMBER OF NUCLEIC ACID SEQUENCES IS FUTILE), RESTRICTION FOR EXAMINATION PURPOSES AS INDICATED IS PROPER.

***FURTHER RESTRICTION- (THIS IS NOT A SPECIES ELECTION)***

CLAIMS 1, 23, 36, 49, 58, 68, AND 78-80 RECITE THE PHRASE "... A CIS ELEMENT SEQUENCE COMPRISING ONE OR MORE COPIES OF A CIS ELEMENT TO WHICH A TRANSCRIPTION FACTOR IS CAPABLE OF BINDING, *THE CIS ELEMENT SEQUENCE VARYING* WITHIN THE LIBRARY..."

THUS, SAID CLAIMS ARE UNSEARCHABLE, AS THEY READ ON AN INFINITE NUMBER OF NUCLEIC ACID SEQUENCES OF INDETERMINATE LENGTH AND COMPOSITION. UPON SELECTION OF ANY OF GROUPS I-VI, APPLICANT MUST FURTHER ELECT A SPECIFIC SUBGENERIC COMPOSITION OF CIS ELEMENTS (E.G., AS DISCLOSED IN FIGURE 2 OF THE SPECIFICATION) FOR PROSECUTION ON THE MERITS.

MOREOVER, ELECTION OF A PROMOTER SEQUENCE 3' TO A CIS ELEMENT, A REPORTER SEQUENCE 3' TO A CIS ELEMENT (E.G., AS DISCLOSED IN FIGURE 2 OF THE SPECIFICATION)), AND A "CIS ELEMENT SEQUENCE-GIVEN REPORTER SEQUENCE" COMBINATION (SEE CLAIM 1, LINES 8-9) IS REQUIRED FOR PROSECUTION ON THE MERITS.

WITH REGARD TO VARIANTS THAT MAY ENCOMPASS:

- A) REPORTER SEQUENCES COMPRISING PRIMING SEQUENCES 5' AND 3' RELATIVE TO THE VARIABLE SEQUENCES, AND WHETHER SAID PRIMING SEQUENCES ARE CONSERVED WITHIN THE LIBRARY,
- B) A NUMBER OF DIFFERENT CIS ELEMENTS (E.G., 10, 20, 50, 100),
- C) A NUMBER OF COPIES OF CIS ELEMENTS (E.G., 2, 3, 4),
- D) A CIS ELEMENT LENGTH (E.G., 5-100, 5-75, 5-50),

ART UNIT: 1639

- E) A LOWER LIMIT ON VARIABLE SEQUENCE LENGTH OF THE REPORTER (E.G., 15, 25, 50 BASE PAIRS),
- F) AN UPPER LIMIT ON VARIABLE SEQUENCE LENGTH OF THE REPORTER,
- G) A NUMBER OF DIFFERENT REPORTER SEQUENCES,
- H) A NUMBER OF DIFFERENT REPORTER PROTEINS,

APPLICANT MUST ELECT A SINGLE VARIANT FOR EACH OF THE ABOVE ELECTED CATEGORIES (A)-(H).

CLAIMS 49, 58, AND 68 RECITE THE PHRASE "... A LIBRARY OF HYBRIDIZATION PROBES FOR DETECTING ... A *PLURALITY OF THE VARIABLE SEQUENCES* OF THE REPORTER SEQUENCES..."

THUS, SAID CLAIMS ARE UNSEARCHABLE, AS THEY READ ON AN INFINITE NUMBER OF NUCLEIC ACID SEQUENCES OF INDETERMINATE LENGTH AND COMPOSITION. UPON SELECTION OF ANY OF GROUPS IV-VI, APPLICANT MUST FURTHER ELECT A SPECIFIC SUBGENERIC COMPOSITION OF HYBRIDIZATION PROBES (E.G., AS DEFINED BY A TARGET SEQUENCE COMPLEMENT TO WHICH A PROBE SHARES A SIGNIFICANT DEGREE OF SEQUENCE IDENTITY (E.G.,  $\geq 75\%$ )) FOR PROSECUTION ON THE MERITS.

APPLICANT IS ADVISED THAT THE REPLY TO THIS REQUIREMENT TO BE COMPLETE MUST INCLUDE AN ELECTION OF THE INVENTION TO BE EXAMINED EVEN THOUGH THE REQUIREMENT BE TRAVERSED (37 CFR 1.143).

APPLICANT IS REMINDED THAT UPON THE CANCELLATION OF CLAIMS TO A NON-ELECTED INVENTION, THE INVENTORSHIP MUST BE AMENDED IN COMPLIANCE WITH 37 CFR 1.48(b) IF ONE OR MORE OF THE CURRENTLY NAMED INVENTORS IS NO LONGER AN INVENTOR OF AT LEAST ONE CLAIM REMAINING IN THE APPLICATION. ANY AMENDMENT OF INVENTORSHIP MUST BE ACCOMPANIED BY A REQUEST UNDER 37 CFR 1.48(b) AND BY THE FEE REQUIRED UNDER 37 CFR 1.17(ii).

ART UNIT: 1639

*ELECTION OF SPECIES*

THE CLAIMS OF GROUPS I-VI ARE GENERIC TO A PLURALITY OF DISCLOSED PATENTABLY DISTINCT SPECIES COMPRISING:

- A. REPORTER SEQUENCES
- B. REPORTER PROTEINS
- C. EXPRESSION VECTORS
- D. MAMMALIAN EXPRESSION VECTORS

APPLICANT IS REQUIRED UNDER 35 U.S.C. 121 TO ELECT A SINGLE SPECIES, EVEN THOUGH THIS REQUIREMENT IS TRAVERSED.

THE SPECIES MENTIONED ABOVE HAVE DIFFERENT AND SEPARATELY BURDENSOME MANUAL AND/OR COMPUTER STRUCTURE, NAME, AND BIBLIOGRAPHICAL SEARCHES, AND HAVE DIVERGENT SUBJECT MATTER.

APPLICANT IS ADVISED THAT A REPLY TO THIS REQUIREMENT MUST INCLUDE AN IDENTIFICATION OF THE SPECIES THAT IS ELECTED CONSONANT WITH THIS REQUIREMENT, AND A LISTING OF ALL CLAIMS READABLE THEREON, INCLUDING ANY CLAIMS SUBSEQUENTLY ADDED. AN ARGUMENT THAT A CLAIM IS ALLOWABLE OR THAT ALL CLAIMS ARE GENERIC IS CONSIDERED NONRESPONSIVE UNLESS ACCOMPANIED BY AN ELECTION.

UPON THE ALLOWANCE OF A GENERIC CLAIM, APPLICANT WILL BE ENTITLED TO CONSIDERATION OF CLAIMS TO ADDITIONAL SPECIES WHICH ARE WRITTEN IN DEPENDENT FORM OR OTHERWISE INCLUDE ALL THE LIMITATIONS OF AN ALLOWED GENERIC CLAIM AS PROVIDED BY 37 CFR 1.141. IF CLAIMS ARE ADDED AFTER THE ELECTION, APPLICANT MUST INDICATE WHICH ARE READABLE UPON THE ELECTED SPECIES. MPEP § 809.02(A).

SHOULD APPLICANT TRAVERSE ON THE GROUND THAT THE SPECIES ARE NOT PATENTABLY DISTINCT, APPLICANT SHOULD SUBMIT EVIDENCE OR IDENTIFY SUCH EVIDENCE NOW OF RECORD

ART UNIT: 1639

SHOWING THE SPECIES TO BE OBVIOUS VARIANTS OR CLEARLY ADMIT ON THE RECORD THAT THIS IS THE CASE. IN EITHER INSTANCE, IF THE EXAMINER FINDS ONE OF THE INVENTIONS UNPATENTABLE OVER THE PRIOR ART, THE EVIDENCE OR ADMISSION MAY BE USED IN A REJECTION UNDER 35 U.S.C. 103(A) OF THE OTHER INVENTION.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DEVON R BYRD WHOSE TELEPHONE NUMBER IS 703-305-0159. THE EXAMINER CAN NORMALLY BE REACHED ON MON-FRI 8A-5P.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, ANDREW WANG CAN BE REACHED ON 703-306-2317. THE FAX PHONE NUMBER FOR THE ORGANIZATION WHERE THIS APPLICATION OR PROCEEDING IS ASSIGNED IS (703) 872-9306.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE RECEPTIONIST WHOSE TELEPHONE NUMBER IS 703-308-1235.

DB  
OCTOBER 15, 2003

BENNETT CELSA  
PRIMARY EXAMINER

